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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
VIVLEMORE, TRACY ANN	

ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 01/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/287,061	CAMMARATA ET AL.	
	Examiner	Art Unit	
	Shobha Kantamneni	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 October 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *13-17 and 19-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *NONE* is/are allowed.

6)☒ Claim(s) *13-17, 19-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The Amendment received on 10/14/05, amended claim 13 by deleting the transitional phrase "comprises" and substituting the phrase "consists essentially of".

Currently, Claims 13-17, and 19-24 are pending.

Applicant's arguments are not persuasive, and the rejection of claims 13-17, 19-21 under 35 U.S.C. 102(e) as being anticipated by Chen et al. (US 6,383,471, PTO 892) is MAINTAINED. See under response to arguments.

Applicant's arguments are not persuasive, and the rejection of claims 13-17, 19-24 under 35 U.S.C. 103(a) as being unpatentable over Jonsson et al. (US 5,383,600, PTO-892 of Record) in view of Chen et al. (US 6,383,471, PTO-892) is MAINTAINED. See under response to arguments.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The instant invention is directed to a pharmaceutical composition in the form of inhalable or insufflable preparation comprising an antimuscarnic agent together with an acceptable carrier for treating urinary disorder in a mammal.

Claims 13-17, 19-21 are rejected under 35 U.S.C. 102(e) as being anticipated by Chen et al. (US 6,383,471, PTO 892).

Chen et al. disclose a pharmaceutical composition comprising a therapeutic agent such as an antimuscarinic agent tolterodine, and pharmaceutically acceptable carriers. See column 7, lines 50-53; column 8, line 59; and column 47, claim 12. Pharmaceutical compositions with water as a carrier are disclosed. See column 34, lines 62-67. It is disclosed that pharmaceutical compositions can be formulated for topical, transdermal, ocular, pulmonary, parental administration etc. It is further disclosed that the pharmaceutical compositions can be formulated in the form of inhalable or insufflable preparation such as a spray or an aerosol or multiparticulates. See column 35, lines 9-23; column 58, claim 107.

Thus Chen et al. anticipate the instant claims 13-17, and 19-21.

The recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 312 F.2d 937, 939, 136 USPQ 458, 459 (CCPA 1963)

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The instant invention is directed to a pharmaceutical composition in the form of inhalable or insufflable preparation comprising an antimuscarnic agent such as tolterodine, together with an acceptable carrier for treating urinary disorder in a mammal.

Claims 13-17, 19-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jonsson et al. (US 5,383,600, PTO-892 of Record) in view of Chen et al. (US 6,383,471, PTO-892).

Jonsson et al. teach pharmaceutical compositions comprising the compounds of 3,3-diphenylpropylamines including the compound tolterodine of the instant invention in association with compatible pharmaceutically acceptable carrier materials, or diluents know in the art. See column 7, lines 47-55; column 33, Table 1, substance 4; column 28, EXAMPLE 22. The pharmaceutical compositions can be made up in solid or liquid form for oral administration, such as tablets, capsules, powders, syrups, elixirs, in the form of sterile solutions, suspensions or emulsions for parenteral administration. Jonsson further teaches that the compounds and compositions can be used for treating cholin-mediated disorders such as urinary incontinence. The daily dosage maybe from

about 0.05 mg to 4 mg per kilo of body weight, administered in one or more doses containing 0.05 to 200 mg. See column 7 lines 67-column8, lines 14.

Jonsson et al. does not specifically teach pharmaceutical formulation in the form of inhalable or insufflable preparation comprising antimuscarinic agent.

Chen et al. as discussed above teaches pharmaceutical composition that can be in the form of inhalable preparation such as aerosol comprising antimuscarinic agent, tolterodine.

From the teachings of Chen et al. it would have been obvious to a person of ordinary skill in the art at the time of the invention to obtain a pharmaceutical formulation in the form of aerosol comprising antimuscarinic agent, tolterodine.

One having ordinary skill in the art at the time the invention was made would have been motivated to obtain a pharmaceutical formulation comprising tolterodine in the form of aerosol with the expectation of obtaining more flexibility in administering the pharmaceutical composition for treating urinary disorders.

Response to Arguments

102 (e) Rejection:

Applicant's argument that "the claims as amended, do not read on formulations comprising an ionizable therapeutic agent, such as tolterodine, and a carrier comprising a required ionizing agent and a surfactant. In direct contrast to Chen, et al., the novel aspect of the present invention is that the instant insufflable formulations do not require any solubilizing components" is not persuasive because the instant claims are directed

to a composition wherein the composition consists essentially of therapeutic agent such as tolterodine, as well as inhalably or insufflably acceptable salts thereof, and Chen also discloses a composition which can be in the form of aerosol, comprising tolterodine, a carrier comprising the ionizing agent, wherein the ionizing agents are selected from inorganic and organic acids (see column 11, lines 39-54), and a surfactant. The ionizing agent used by Chen et al., results in a pharmaceutically acceptable salt of N-substituted aromatic amines such as tolterodine by protonating the basic amine functional group of tolterodine, see column 6, lines 1-5; column 11, lines 36-39, and thus the compositions of Chen et al. comprises a pharmaceutically acceptable salt of tolterodine, and a surfactant which meets the instant claims. Thus, Chen et al. disclose an antimuscarnic agent and an inhalably or insufflably acceptable carrier.

It is respectfully pointed out that for the purposes of searching for and applying prior art under 35 USC 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to comprising. If an applicant contends that additional steps or material in the prior art are excluded by the recitation of "consisting essentially of ", applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant's invention. See MPEP 2111.03.

103 Rejection:

See under 102(e).

Conclusion

THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period, will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shobha Kantamneni whose telephone number is 571-272-2930. The examiner can normally be reached on Monday-Friday, 8am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Shobha Kantamneni, Ph.D
Patent Examiner
Art Unit 1671

SHENGJUN WANG
PRIMARY EXAMINER